

Ethical issues arising in research with people with mental health conditions

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Governance paper

Tensions between the UN CRPD and CIOMS Guidelines: implications for fair inclusion of individuals living with psychosocial disabilities in research

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Short description

Analysis of influential international ethical guidelines and international human rights treaty

Commentary

In this paper, I analyze the divergence between international ethical guidelines developed by the Council for International Organizations of Medical Sciences (CIOMS)¹ and the United Nations' Convention on the Rights of Persons with Disabilities (CRPD)². Broadly, the CIOMS guidelines, while progressive, retain a key function as necessarily *safeguarding* individuals living with psychosocial disabilities, whereas the CRPD can be understood as *empowering* individuals living with psychosocial disabilities. I first explore tensions between CIOMS guidelines and the CRPD in light of these divergent underlying philosophies; I then consider the extent to which these tensions should concern the research enterprise. I conclude that finding resolutions to these tensions rests on our understanding of fair inclusion in research for individuals living with psychosocial disabilities.

Background

Adopted in 2006 and ratified in 2008, the CRPD offers a robust framework for recognizing the rights of persons with disabilities, including individuals with 'long-term mental impairments'². A key aspect of the CRPD is its guarantee of the right to universal legal capacity for all individuals living with disabilities. Though this right to universal legal capacity has been much debated in the literature (e.g. Freeman et al. 2015, Appelbaum 2019, Scholten and Gather 2018³⁻⁵), the Committee on the Rights of Persons with Disabilities reaffirmed in their General Comment No. 1 that legal capacity is, in fact, an absolute right that must be afforded to every individual, and that substituted decision-making of any kind contravenes the CRPD⁶. Additional protections afforded in the CRPD include the right to equality, non-discrimination on the basis of disability, the right to full participation in society, and the right to the highest attainable standard of health.

The 2016 CIOMS guidelines afford a different set of protections, specifically related to involvement in health research. CIOMS guidelines broadly support highly inclusive target populations across studies. The guidelines also highlight that a diagnosis of "mental and behavioural disorders" does not necessarily imply incapacity to consent¹. Though the guidelines move away from classifying groups of populations as inherently vulnerable, Guideline 16 suggests that "some psychiatric conditions" can cause incapacity, in which case surrogate decision-making is permitted¹.

Tensions

These guarantees appear to have critical implications for the research enterprise. Though the CRPD does not explicitly guarantee a *right* to participate in research (discussed later), several of its core principles, especially in light of the CRPD's guarantee to the right to health, might warrant consideration in the design and conduct of health research of any kind. To better understand these implications, I identify a few tensions between CIOMS and the CRPD with regard to research participation and highlight key questions that warrant further deliberation.

1. Surrogate decision-making and informed consent

Though surrogate or substitute decision-making is prohibited by the CRPD, CIOMS allows for surrogate decision-making for individuals who are unable to consent. To uphold the principles of the CRPD, specifically universal legal capacity, the research enterprise should not accept surrogate decision-making. However, research with individuals who are unable to consent to participation may yield valuable scientific knowledge, or individual benefit to them. *When the prospect of individual or community benefit outweighs potential risks, should surrogate decision-making be permissible to consent to participate, per CIOMS, even though it violates the CRPD?*

2. Non-discrimination and participant selection

The CRPD's principle of non-discrimination could have important implications for participant selection. Generally, the principle of non-discrimination has been invoked in response to concern that participants are excluded from research solely on the basis of a social characteristic (e.g. disability, as well as race, gender, pregnancy, age, et cetera). Given historical classifications of individuals with psychosocial disabilities as 'vulnerable', researchers (and research ethics committees) may categorically exclude individuals with psychosocial disabilities from participation at the outset of a study, directly contradicting the CRPD. However, there may be cases in which inclusion of individuals with psychosocial disabilities on the same basis as others may be considered scientifically inadvisable (e.g. testing a drug that might react with a routinely prescribed psychiatric medication). *How do we ensure that "reasonably justified" exclusion criteria, per CIOMS, do not violate the CRPD's non-discrimination principle, while recognizing that the categorical exclusion of individuals living with psychosocial disabilities is discriminatory?*

3. "Vulnerability" and psychosocial disability

Per CIOMS, individuals living with psychosocial disabilities are potentially vulnerable in the context of research participation, specifically in terms of capacity to consent, though CIOMS also makes clear that "diagnosis of a mental or behavioural disorder does not necessarily imply that individuals are incapable of giving informed consent"¹. That said, capacity tests are widely considered to violate the CRPD⁷, and determining inability to consent on the basis of disability (as implied in CIOMS Guideline 16) is discriminatory per CRPD standards. *How then should we understand which individuals living with psychosocial disabilities—if any—are "vulnerable" from a research participation perspective, even if such a designation contravenes the CRPD?*

Conclusion

To resolve these tensions between the CRPD and CIOMS, we must come to a shared understanding of what fair research participation entails. CIOMS does not guarantee the 'right to participate' in research, (though, arguably, CIOMS offers an implicit 'right' not to be *unjustly excluded* on the basis of a social category)¹. The CRPD also does not guarantee an explicit 'right to participate' in research², though some commentators have argued that the text of the Convention does imply the right to participate in research⁸.

My proposal to resolve the tensions between the CRPD and CIOMS rests on my view that the CRPD implies a right to *benefit* from research (which, critically, does not necessarily entail participation in research) as opposed to a right to *participate* in research. That is, while research *participation* should not be understood as a component of the 'right to full participation in society' as guaranteed in the CRPD, the right to benefit from research *should* be. I suggest that CRPD principles should apply to the research *agenda* as a whole, but not necessarily to research *studies* individually.

Recommendation

Based on this understanding of justice in research participation, I suggest that the CRPD should differentially matter to the research enterprise depending on the purpose of the research. However, *all research* should accept that presence of mental illness does *not* imply incapacity.

For research intended to be generalizable population-wide, individuals with psychosocial disabilities should be included *as part of* the general population. In these instances, the research

enterprise should respect the principle of non-discrimination by *not* excluding on the basis of mental illness. However, this provision does not necessarily afford the *right* to participate in any 'general population' study (e.g. a Phase III vaccine efficacy trial); rather, it is intended to ensure accurate representation of the true population to maximize the validity of study findings (e.g. an implementation study for a flu vaccine rollout).

For research intended to apply to a specific group of individuals living with psychosocial disabilities, the research enterprise should ensure that assessments of capacity are not based on disability, but rather on general principles for informed consent in research. Furthermore, should someone be unable to provide informed consent in a specific instance, studies should *not* accept surrogate decision-making for participation, in line with CRPD principles.

References

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